

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application

Inventor(s): James F. Zucherman, Ken Y. Hsu, Charles J.

Winslow, John Flynn, Steve Mitchell

Appln. No.: 10/694,103

Confirm. No.: 3095

Filed: October 27, 2003

Title: INTERSPINOUS PROCESS IMPLANT WITH

RADIOLUCENT SPACER AND LEAD-IN TISSUE

EXPANDER

PATENT APPLICATION

Art Unit:

3731

Examiner:

Customer No.: 23910

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that my residence, mailing address and citizenship are as stated below next to my name. I believe that I am the original, first and sole inventor (if one name is listed below), or first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

INTERSPINOUS PROCESS IMPLANT WITH RADIOLUCENT SPACER AND LEAD-IN TISSUE EXPANDER

the specification of which ((check applicable ones):
	is filed herewith;
	was filed with the above-identified "Filed" date and "Appln. No."
	was amended on (or amended through)

I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) referred to above. I acknowledge the duty to disclose information which is material to the examination of the application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

BEST AVAILABLE COPY

or first inventor:	James F. Zucherman
1) Residence: 2	035 Pine Street, San Francisco, CA 94123
1) Mailing Address:	SAME
(1) Citizenship:	Lynn - MMD
(1) Inventor's signature	: XIBSON F / P. J.
(1) Date:	H/py "
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(2) Full name of secon joint inventor:	
(2) Residence:	52 Clarendon Avenue, San Francisco, CA 94114
(2) Mailing Address: _	SAME
(2) Citizenship:	US
V-/	
(2) Inventor's signature	e la
(2) Date:	6/1/2004

(3) Full name of third joint inventor: Charles J. Winslow (3) Residence: 25 Hilton Ct., Walnut Creek, CA 94595 (3) Mailing Address: SAME (3) Citizenship: US (3) Inventor's signature: __ (4) Full name of fourth joint inventor: John Flynn (4) Residence: 1458 Santa Clara Ave., Concord, CA 94519 (4) Mailing Address: <u>SAME</u> (4) Citizenship: US (4) Inventor's signature: (4) Date: __

(5) Full name of fifth joint inventor:	Steve Mitchell
(5) Residence:	776 Duke Circle, Pleasant Hill, CA 94523
(5) Mailing Address: _	SAME
(5) Citizenship:	US
(5) Inventor's signature	
(5) Date:	3-30-04

Title 37, Code of Federal Regulations, §1.56

SECTION 1.56. DUTY TO DISCLOSE INFORMATION MATERIAL TO PATENTABILITY

- (a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§1.97(b)-(d) and 1.98.* However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:
 - (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
 - (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.
- (b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office; or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

- (c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:
 - (1) Each inventor named in the application;
 - (2) Each attorney or agent who prepares or prosecutes the application; and
 - (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.
- * §§1.97(b)-(d) and 1.98 relate to the timing and manner in which information is to be submitted to the Office.